

237786
RECORD NO.

14504
SHAUGHNESSEY NO.

DER
fathead - Daphnia life-cycle

3-22-89

49

REVIEW NO.

EEB REVIEW

DATE: IN 01/13/89

OUT 03/22/89

FILE OR REG. NO 707-78

PETITION OR EXP. NO

DATE OF SUBMISSION: 12/21/88

DATE RECEIVED BY HED: 1/11/89

RD REQUESTED COMPLETION DATE: 03/15/89

EEB ESTIMATED COMPLETION DATE: same as above

RD ACTION CODE/ TYPE OF REVIEW: 660

TYPE PRODUCT(S): Fungicide

ACCESSION NUMBER(S): 407862-01-02

PRODUCT MANAGER: L. Rossi (21)

PRODUCT NAME(S): Dithane M-45 (mancozeb)

COMPANY NAME: Rohm and Haas

PURPOSE OF SUBMISSION: Chronic aquatic toxicity studies on
fathead minnow and Daphnia



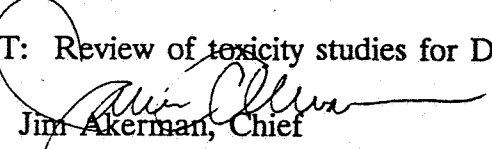
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PESTICIDE PROGRAMS

ENVIRONMENTAL FATE AND EFFECTS DIVISION

MEMORANDUM

SUBJECT: Review of toxicity studies for Dithane M-45

FROM: 
Jim Akerman, Chief
Ecological Effects Branch (H7507-C)
Environmental Fate and Effects Division

TO: Lois Rossi, Product Manager 21
Registration Division (H7505-C)

The mancozeb Registration Standard requires a fish early life stage and an invertebrate chronic study. Rohm and Haas Company submitted two documents to fulfill these requirements. The following document was found to be invalid on 14 October 1988:

1. McAllister, W. 1988. Early life stage toxicity of Dithane M-45 to fathead minnows (Pimephales promelas) in a flow through system. Prepared by ABC Laboratories, Inc. Columbia, MO Submitted by Rohm and Haas Spring House, PA. MRID: 407862-02.

The purpose of this study was to determine the maximum allowable toxicant concentration (MATC) for the test species. The MATC is defined as the range of concentration between the lowest concentration that has a statistically significant effect ($\alpha \leq 0.05$) on any measured response, and the next lower concentration having no significant effect. Because significant mortality occurred at all test concentrations, it is not possible to determine a maximum allowable toxicant concentration. Therefore, the study is invalid for a determination of the toxicity of Dithane M-45 to the early-life-stage of fathead minnow.

Our review of this report has been questioned by ABC Laboratories in their present submission. ABC Laboratories' statistical arguments are faulty, but more importantly, are based upon discarding part of their data. When these data are discarded ABC's statistical test shows no significance for the penultimately low concentration. However, ABC Laboratories is not justified in discarding data to avoid statistical significance. The test must be repeated.

The following study was reviewed with this submission: .

2. Chronic toxicity of Dithane M-45 to Daphnia magna under flow-through test conditions. Performed by Analytical Bio-Chemistry Laboratories, July 29, 1988. MRID number: 407862-01.

This study is scientifically sound, and was performed under conditions that generally comply with current guideline standards.

CONCURRENCES

SYMBOL	H7507C H7507C					
SURNAME	John Croen					
DATE	22 March 87 3/23/89					

DATA EVALUATION RECORD

1. CHEMICAL: Dithane M-45

SN: 14504

2. TEST MATERIAL: TGAI 82.4%

3. STUDY/ACTION TYPE: 21 day life cycle study with daphnids

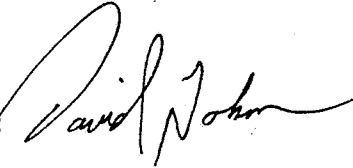
4. STUDY IDENTIFICATION:

Burgess, D. 1988. Chronic toxicity of Dithane M-45 to Daphnia magna under flow through test conditions. Prepared by ABC Laboratories, Inc. Columbia, MO. Submitted by Rohm and Haas Spring House, PA. MRID: 409538-02.

5. REVIEWED BY:

David Johnson, Fishery Biologist
Ecological Effects Branch

Signature:

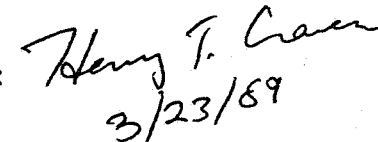


Date: 22 March 89

6. APPROVED BY:

Harry Craven, Head, Section 4
Ecological Effects Branch

Signature:



Date:

3/23/89

7. CONCLUSIONS:

This study is scientifically sound, and generally complies with the guideline requirements.

8. RECOMMENDATION:

9. BACKGROUND: n/a

10. DISCUSSION OF INDIVIDUAL STUDIES OR TESTS: n/a

11. METHODS AND MATERIALS:

Source. in house daphnid culture

Food. The food source was algae supplemented with Tetramin.

Test water

Temperature: 20+₂°C

Water source and chemistry: well water.

The properties of the adjusted water are:

Hardness= 4160-180 mg/L total, pH= 7.5

Solvent: none

Controls: A Control was run concurrent with the test.

Test System.

Vessel Size/Volume: 1L beakers.

Flow rate: 4.1 ml/min/replicate

Vessel Construction: Glass

Photoperiod: 16h-light/8h-dark

Number of organisms/concentration: 10/vessel, 40/conc

Test Levels: nominal: 3, 5.9, 12, 25, 50, 5000 µg/L
measured: throughout the study

Toxic signs. immobility, length, time until first brood.

Statistical analysis. ANOVA and Dunnetts.

12. REPORTED RESULTS:

Data

The data were included with the study report.

Analysis of Test Concentrations Analyses of the test concentrations were performed.
Results are reported by measured concentrations.

13. STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:

MATC based on time to first brood: >7.3 and <12.0 µg/l ✓

14. REVIEWER'S DISCUSSION AND INTERPRETATION OF THE STUDY:

A. Test Procedure.

This study was performed under conditions that generally comply with current Guideline standards.

B. Statistical Analysis.

C. Results/Discussion.

The Ecological Effects Branch concurs with the study authors' conclusions.

D. Adequacy of the Study.

1. Category: core

2. Rationale: n/a

3. Remedy: n/a

E. COMPLETION OF ONE LINER 22 March 1989

Mancozeb

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Pages _____ through _____ are not included.

The material not included contains the following type of information:

- ☐ Identity of product inert ingredients.
- ☐ Identity of product impurities.
- ☐ Description of the product manufacturing process.
- ☐ Description of quality control procedures.
- ☐ Identity of the source of product ingredients.
- ☐ Sales or other commercial/financial information.
- ☐ A draft product label.
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